

### **REMARKS**

This application has been reviewed in light of the Office Action dated November 20, 2003. Claims 1, 3-11 and 14-30 are pending in the application. Claims 1 and 19 are amended in a manner that Applicant believes overcome the rejections in the Office Action. Support for the amendments can be found throughout the specification and figures of the present disclosure and recite aspects of the disclosure that Applicant is believed to be entitled. Applicant submits that no new matter or issues are introduced by the amendments.

Initially, Applicant gratefully acknowledges the allowability of the subject matter recited in claim 30. Applicant, however, respectfully submits that in view of the amendments and remarks herein, all claims presently pending in the application are allowable over the art of record.

In the Office Action, claims 1, 3-5 and 18-23 were rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,494,590 to Smith et al. (Smith '590). Claims 14-17 and 24-29 were also rejected under 35 U.S.C. §103(a) over the Smith '590 patent. However, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, independent claim 4, claims 5 and 14-18 depending therefrom, amended independent claim 19, claim 20 depending therefrom, independent claim 21 and claims 22-29 depending therefrom, clearly and patentably distinguish over the Smith '590 patent.

One of the important distinctions of the present application over the prior art is dispensing thixotropic gel, in contemplation for performing a centrifugation, along predetermined or calculated limits of the inner surface of a collection tube. This configuration results in several advantages including limited migration of the gel, stronger mechanical barrier and lower gel quantity requirements.

Referring to the Figure shown, the Smith '590 patent discloses a blood separation assembly having an anticoagulant 18, a thixotropic gel 14 disposed below anticoagulant 18, and a separation medium 16 disposed below gel 14. (col. 8, lines 20-68). A quantity of this combination of components is disposed within a tube 12 such that there is enough free space 20 for a blood sample. (col. 9, lines 28-30). The Smith '590 patent does not teach, motivate, or suggest anything

predetermined or calculated about the distance for dispensing the gel along the inner surface of the tube.

In contrast, amended claim 1 of the present application recites, *inter alia*, "...[a] blood collection apparatus comprising... gel being selectively deposited and radially contiguous on the inner surface, and displaced a predetermined distance relative to the end, said predetermined distance based on at least one dimension of the blood collection tube and a volume of the blood sample being collected." Amended claim 4 recites, *inter alia*, "... gel being deposited on and radially contiguous on the central inner surface and displaced a distance relative to the closed end, said distance based on the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end..." Amended claim 19 recites, *inter alia*, "... gel being deposited on and radially contiguous on a predetermined portion of the central inner surface and displaced a predetermined distance relative to the closed end..." Amended method claim 21 recites, *inter alia*, "... providing a dispensing apparatus configured to dispense a thixotropic gel... being deposited and radially contiguous along a portion of the central inner surface and displaced a distance relative to the closed end, said distance based on the portion of the central inner surface defining a predetermined first limit and a predetermined second limit relative to the end..."

The Smith '590 patent in no way discloses or suggests a structure as recited in claims 1, 4 and 19, or a method as disclosed in method claim 21. The Smith '590 patent does not disclose, *inter alia*, a gel being selectively deposited and radially contiguous on the inner surface of a tube, and displaced a predetermined distance, within predetermined limits, relative to the end. The predetermined distance being based on at least one dimension of the blood collection tube and a volume of the blood sample being collected. Rather, the Smith '590 patent shows an order for blood separation components and that, apart from the components, there should be enough space left in the tube for the blood sample.

Because of the above distinctions, it is respectfully submitted that amended independent claim 1, claim 3 depending therefrom, independent claim 4, claims 5 and 14-18 depending

therefrom, amended independent claim 19, claim 20 depending therefrom, independent claim 21 and claims 22-29 depending therefrom are patentable and not obvious over the Smith '590 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claims 6-10 were rejected under 35 U.S.C. §103(a) over the Smith '590 patent in view of U.S. Patent No. 3,516,385 to Walling (Walling '385). However, it is respectfully submitted that independent claim 4, from which claims 6-10 depend, clearly and patentably distinguishes over the Smith '590 patent in any combination with the Walling '385 patent.

The Smith '590 patent has been discussed. Referring to FIGS. 4A and 5, the Walling '385 patent discloses an apparatus for coating the interior of tubular members via nozzles 59. (col. 7 line 41- col. 9, line 50). The Walling '385 patent in no way discloses or suggests structure as recited in claim 4, from which claims 6-10 depend. The Walling '385 patent does not cure the deficiencies of the Smith '590 patent in that the Walling '385 patent does not disclose, *inter alia*, a gel being selectively deposited and radially contiguous on the inner surface of a tube, and displaced a predetermined distance, within predetermined limits, relative to the end. The predetermined distance being based on at least one dimension of the blood collection tube and a volume of the blood sample being collected.

Because of the above distinctions, it is respectfully submitted that independent claim 4, from which claims 6-10 depend, is patentable and not obvious over the Smith '590 patent in any combination with the Walling '385 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In the Office Action, claim 11 was rejected under 35 U.S.C. §103(a) over the Smith '590 patent in view of U.S. Patent No. 4,257,886 to Kessler (Kessler '886). However, it is respectfully submitted that independent claim 4, from which claim 11 depends, clearly and patentably distinguishes over the Smith '590 patent in any combination with the Kessler '886 patent.

The Smith '590 patent has been discussed. Referring to FIG. 1, Kessler '886 shows a gel-like material 28 loosely disposed near a closed end 16 of a container 12 and a hydrophobic coating

30. (col. 2, lines 47-65). The Kessler '886 patent in no way discloses or suggests structure as recited in claim 4, from which claim 11 depends. The Kessler '886 patent does not cure the deficiencies of the Smith '590 patent in that the Kessler '886 patent does not disclose, *inter alia*, a gel being selectively deposited and radially contiguous on the inner surface of a tube, and displaced a predetermined distance, within predetermined limits, relative to the end. The predetermined distance being based on at least one dimension of the blood collection tube and a volume of the blood sample being collected.

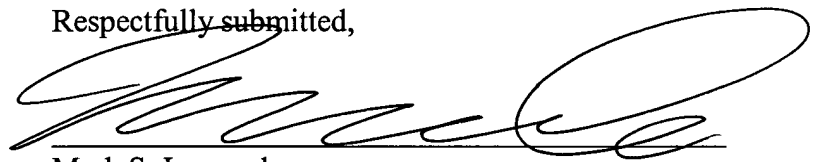
Because of the above distinctions, it is respectfully submitted that independent claim 4, from which claim 11 depends, is patentable and not obvious over the Smith '590 patent in any combination with the Kessler '886 patent. Reconsideration and withdrawal of the rejections are respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1, 3-11 and 14-30 presently pending in the application are believed to be in condition for allowance and patentably distinguish over the art of record. An early notice thereof is earnestly solicited.

If the Examiner should have any questions concerning this communication or feels that an interview would be helpful, the Examiner is requested to call the Applicant's undersigned attorney.

Please charge any deficiency as well as any other fees that may become due at any time during the pendency of this application, or credit any over payment of such fees to deposit account no. 50-0369. Also, in the event that any extensions of time for responding are required for the pending application, please treat this paper as a petition to extend the time as required and charge deposit account no. 50-0369 therefor.

Respectfully submitted,



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